

Essentiale® FORTE 300 mg

Soybean phospholipids
Hard capsules

sanofi aventis

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after a few days.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What ESSENTIALE FORTE 300 mg hard capsules are and what they are used for
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1. WHAT ESSENTIALE FORTE 300 mg HARD CAPSULES ARE AND WHAT THEY ARE USED FOR

Essentiale Forte 300 mg is an herbal medicine for liver diseases.

Essentiale Forte 300 mg is used to improve subjective symptoms, such as loss of appetite or a feeling of pressure in the upper right abdomen, in patients with liver damage caused by substances harmful to the liver as well as poor diet (toxic effects of certain foods) and in those with chronic liver inflammation (hepatitis).

2. BEFORE YOU TAKE ESSENTIALE FORTE 300 mg HARD CAPSULES Do not take ESSENTIALE FORTE 300 mg

- if you have a known allergy to preparations containing soybeans or to any of the other ingredients in this medicine.

This medicine contains soy oil. In rare cases, it may therefore cause severe allergic reactions.

Take special care with Essentiale Forte 300 mg

- if symptoms worsen or if other unclear symptoms appear. In this case, you should consult a doctor.

This medicinal treatment is not a substitute for avoiding substances that damage the liver (e.g. alcohol).

If you have chronic hepatitis, supportive treatment with soybean phospholipids is only justified if an improvement in the subjective signs of your condition is observed under treatment.

Children

Sufficient studies are not available concerning use of Essentiale Forte 300 mg in children. It should therefore not be used in children under 12 years of age.

Taking or using other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

An interaction between Essentiale Forte 300 mg and medicines that inhibit coagulation of the blood cannot be ruled out. It may therefore be necessary to adjust the dosage of this medicine. If you are taking Essentiale Forte 300 mg at the same time as this type of medicine, you should consult your doctor.

Pregnant and breast-feeding women

To date, widespread use of soybeans as a foodstuff has yielded no evidence of risks in pregnancy and breast-feeding. Sufficient studies are not available. Therefore, use of this medicine during pregnancy and breast-feeding is not recommended.

Driving and using machines

No specific precautions are required.

3. HOW TO TAKE ESSENTIALE FORTE 300 mg HARD CAPSULES

Always take Essentiale Forte 300 mg exactly as indicated in this package leaflet. If you are unsure of anything, please ask your doctor or pharmacist for advice.

Unless your doctor prescribes otherwise, the usual dosage is as follows:

Age (Bodyweight)	Single dose	Total daily dose
Children from 12 years of age (about 43 kg) Adolescents and adults	2 hard capsules (600 mg soybean phospholipids)	2 hard capsules 3 times daily (1,800 mg soybean phospholipids)

Swallow the capsules whole at meal times with sufficient liquid (preferably a glass of water [200 ml]).

In principle, there is no time limit for how long you can take this medicine. Please consult the information in Section 2.

Please consult your doctor or pharmacist if you think that the effect of Essentiale Forte 300 mg is too strong or too weak.

If you take more Essentiale Forte 300 mg than you should

No symptoms of overdose or poisoning are known for Essentiale Forte 300 mg.

It is possible that the side effects listed below could occur with greater intensity. If this happens, please inform a doctor. He or she can decide whether any measures need to be taken.

If you forget to take Essentiale Forte 300 mg

If you take too little Essentiale Forte 300 mg or forget to take a dose, do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

If you have other questions about taking this medicine, please consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Essentiale Forte 300 mg can cause side effects, although not everybody gets them.

The following categories are used for the frequency of side effects:

Very common: more than 1 in 10 treated patients
Common: 1 to 10 in 100 treated patients
Uncommon: 1 to 10 in 1,000 treated patients
Rare: 1 to 10 in 10,000 treated patients
Very rare: fewer than 1 in 10,000 treated patients
Unknown: frequency cannot be determined based on available data

Significant signs or side effects that you should be aware of and measures to be taken if you have a side effect:

Uncommonly, digestive disorders may occur, such as stomach disorders, soft stools or diarrhea.

Very rarely, allergic reactions can occur, such as skin rash or hives.

Pruritus (itching) may occur; the frequency is not known.

If you notice that you have any of the side effects listed above, particularly allergic reactions, stop taking Essentiale Forte 300 mg and inform your doctor. He or she can determine the severity of the side effect and decide whether any measures need to be taken.

If any of the listed side effects become serious, or if you notice any side effects not listed in this package leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ESSENTIALE FORTE 300 mg HARD CAPSULES

Store this medicine out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after the note "EXP". The expiry date is the last day of the month indicated.

Storage conditions:

Store at a temperature no higher than 25°C.

Store in the original packaging to protect the contents from moisture.

6. FURTHER INFORMATION

What Essentiale Forte 300 mg contains:

The active substance is:

300 mg enriched deoiled soy phospholipids.

The other ingredients are: 96% ethanol, hard fat, soy oil (Ph.Eur.), hydrogenated castor oil, ethyl vanillin, acetanisole, alpha-tocopherol, gelatin, coloring agent E171, 172, sodium dodecyl sulfate, purified water.

What Essentiale Forte 300 mg looks like and contents of the pack:

Standard pack containing 50 hard capsules

Manufacturer

A. Nattermann & Cie. GmbH
Nattermannallee 1
50829 Cologne
Germany

This package leaflet was last revised in August 2009.